

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Ryuichi Morishita et al.

Application No. 09/869,475

Filed: October 10, 2001

Confirmation No. 4309

For: GENE THERAPY FOR DIABETIC
ISCHEMIC DISEASE

Examiner: Brian Whiteman

Art Unit: 1635

Attorney Reference No. 6235-59221-01

CERTIFICATE OF MAILING

I hereby certify that this paper and the documents referred to as being attached or enclosed herewith are being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450 on the date shown below.

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**DECLARATION OF RYUICHI MORISHITA AND
TOSHIO OGIHARA UNDER 37 C.F.R. §1.132 AND MPEP §2132.01**

We, RYUICHI MORISHITA and TOSHIO OGIHARA declare as follows:


1. We are two of the co-inventors of, and have each read and understand, U.S. Patent No. 6,248,722 entitled MEDICAMENT COMPRISING HGF GENE (hereinafter the '722 patent), which issued June 19, 2001.

2. We are named co-inventors of, and have each read and understand, U.S. Patent Application No. 09/869,475 (hereinafter the '475 application) entitled GENE THERAPY FOR DIABETIC ISCHEMIC DISEASE. Claims 9, 11, 12, 14, 23-26, 28-34, and 36-42 were rejected as allegedly being anticipated (under 35 U.S.C. §102(e)) by the teachings of the '722 patent.

3. Any disclosure in the '722 patent relating to a method for the treatment of diabetic ischemic disease in a subject using hepatocyte growth factor gene therapy is solely our own work, and not the work of Toshikazu Nakamura, Tetsuya Tomita and Takahiro Ochi. Thus, to the extent that the '722 patent discloses a method for the treatment of diabetic ischemic disease in a subject, that subject matter is our own work and not that "of another."

4. All statements made herein of our own knowledge are true and all statements made on information and belief are believed to be true; and further, these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that any such willful false statements made may jeopardize the validity of the application or any patent issuing thereon.

Date: 01/26, 2005


Ryuichi Morishita

Date: 01/27, 2005


Toshio Ogihara